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UNITED STATES ENVI IONMENTAL PROTECTION AGENCY

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#253

DATE: Sept. 5, 1980

SUBJECT: PQ-57
EPA Reg. No. 1022-490

FROM: Sherell A. Sterling 9-16-80
FHB/TSS E 9/24/80

TO: Henry Jacoby
Product Manager (21)

Applicant: Chapman Chemical CO.
P.O. Box 9158
Memphis, TN 38109

Active Ingredient:
Copper 8 - quinolinolate..... 5.0%
Inert Ingredients.....95/0%

Background: This is a resubmission of data to justify a change in signa word. These data were submitted under Accession No. 242668, Acute Oral, Eye and Skin Irritation studies were conducted by the Warf Institute of Madison, Wisconsin. An additional Eye Irritation was conducted by Canno Laboratories, Inc. of Reading, PA. The Cite-All method of support is being used.

Recommendations:

1. The Acute Oral study is considered Core Supplementary Data. As such it may not be used to support registration of a product. Please not the following comments concerning this study.

   a. Only male animals were tested; equal numbers of males and females must be tested.

   b. The LD_{50} must be calculated separately for each sex as well as combined male and female.

   c. Dose levels must be spaced to produce test groups with mortality rates between 10% and 90% and to permit the calculation of the LD_{50} for males and females with a 95% confidence interval of 20% or less.

2. The Eye Irritation studies are adequate and acceptable for registration purposes.

3. The Skin Irritation study is adequate and acceptable for registration purposes. However, please note the following comments:

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a. Four sites, 2 abraded and 2 intact sites, must be tested on each animal.

4. FHB/TSS has no objection to the change in signal word from CAUTION to DANGER. No further data are required at this time.

5. Precautionary labeling is acceptable as submitted.

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Review:

1. Acute Oral Toxicity: Warf # 7042670; May 31, 1977

   Procedure: 30 M adult SD rats received a dosage of 1 g/kg, 2 g/kg or 5g/kg of 3426-3 (PQ-57). Animals were observed for 2 weeks. All animals in study were subjected to necropsies.

   Results: Deaths reported were; none at 1g/kg and all animals at 2 g/kg, 5 g/kg. Symptoms in animals with 2 or 5 g/kg were diarrhea. Necropsies revealed: GI tract distended with gas and watery fecal material; mottling of lungs. LD_{50} is "between 1.0 and 2.0 g/kg".

   Study Classification: Core Supplementary Data. Only M rats were tested. Mortality rates were either 0% or 100%.

2. Eye Irritation Study; Warf # 7042670; May 31, 1977

   Procedure: 0.1 ml of 3426-3 (PQ-57) was instilled into one eye of each of 6 New Zealand rabbits. No eyes received wash. Animals were observed for 2 weeks.

   Results: At 24 hours corneal opacity in 2/6=10, 3/6=20 observed; also, redness in 6/6=2, chemosis in 6/6=3 and discharge in 6/6=3. At 7 days corneal opacity observed in 1/6=5, 2/6=10, 4/6=20; redness in 6/6=12; chemosis in 1/6=1, 4/6=2; discharge in 2/6=2, 3/6=3. Corneal opacity observed in 6/6 at day 14; conjunctival irritation also noted.

   Study Classification: Core Minimum Data. No "washed" eyes were studied.

   Toxicity Category: I-DANGER

3. Primary Eye Irritation Study of "PQ-57" on New Zealand Albino Rabbits; Cannon Notebook # CHA-002; December 10, 1979

   Procedure: 9 New Zealand white rabbits each received a dosage of 0.1 ml of PQ-57 in one eye. Twenty seconds after instillation, the treated eye of 3 rabbits was washed with lukewarm water for one minute. Animals were observed for 13 days.

   Results: In the no-wash group by day 7, all eyes showed maximum corneal opacity scores; by day 13, 4/6 exhibited destroyed eyeballs. Iris irritation, redness, chemosis and discharge were noted in all non-washed eyes; also, alopecia was observed. The "wash" eye group showed 2/3 with pannus and 1/3 with the maximum corneal opacity score by day 13; iris irritation, redness, chemosis, discharge were noted in all eyes.

   Study Classification: Core Guidelines Data.

Toxicity Category: I-DANGER

4. Primary Skin Irritation; Warf # 7042670; May 31, 1977

Procedure: 0.5 ml of 3426-3 (PQ-57) was applied to 2 sites (1 abraded, 1 intact) on each of 6 New Zealand rabbits. Animals were scored at 24 and 72 hours.

Results: AT 24 hours, abraded and unabraded all have severe erythema (12/12=4) and "well-defined" edema (12/12=2). AT 72 hours all abraded and unabraded have moderate to severe erythema (12/12=3) and half of each group had slight of "well defined" edema (6/12=1, 6/12=2). The Primary Irritation Index was 5.25.

Study Classification: Core Minimum Data. Only 2 sites instead of 4 sites per animal were tested.

Toxicity Category: II WARNING

Copper 8-quinolinolate Reviews

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